

OCT 29 2009

**510(k) Summary for
INNOVANCE® D-Dimer Assay**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091916

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Siemens Healthcare Diagnostics
Products GmbH
Emil-von-Behring Str. 76
D-35001, Marburg Germany

Contact Information: Siemens Healthcare Diagnostics
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: September 22, 2009

2. Device Name/ Classification: INNOVANCE® D-Dimer

Class: Fibrinogen and Fibrin Split Product, Antigen, Antiserum
and controls, Class II
21 CFR 864.7320
Panel: Hematology (HE)
Product Code: DAP

3. Identification of the Legally Marketed Device:

VIDAS® D-Dimer Exclusion™ – k040882

4. Device Description:

Polystyrene particles covalently coated with a monoclonal antibody (8D3) are aggregated when mixed with samples containing D-dimer. The D-dimer cross-linkage region has a stereosymmetrical structure, i.e. the epitope for the monoclonal antibody occurs twice. Consequently, one antibody suffices in order to trigger an aggregation reaction, which is then detected turbidimetrically via the increase in turbidity.

5. Device Intended Use:

INNOVANCE® D-Dimer:

For the quantitative determination of cross-linked fibrin degradation products (D-dimers) in human plasma on Siemens Healthcare Diagnostics and Sysmex® Coagulation Systems. The INNOVANCE® D-Dimer assay is intended for use in conjunction with a non-high clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease and as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

6. Medical device to which equivalence is claimed and comparison information:

The INNOVANCE® D-Dimer is substantially equivalent to the VIDAS® D-Dimer Exclusion™ (k040882) assay. The INNOVANCE® D-Dimer method, like the VIDAS® D-Dimer Exclusion™ method, is intended for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease.

7. Device Performance Characteristics:

Comparative Method	Slope	Regression Statistics		n
		Intercept (mg/L FEU)	Correlation Coefficient	
VIDAS® D-Dimer Exclusion™	1.11	-0.075	0.96	265

The range of D-dimer values in the correlation studies was 0.17 to 4.17 mg/L FEU.

Clinical Study Summary

The INNOVANCE® D-Dimer assay was evaluated on the BCS® / BCS® XP System in a multi-center study to validate the exclusion of PE using fresh specimens collected from 701 consecutive patients presenting to the emergency department with suspected PE. Of these 701 patients, 54 were excluded for a total of 647 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a high, moderate or low pre-test probability (PTP) of PE. Patient specimens were tested with the INNOVANCE® D-Dimer assay and results were compared to a cutoff value of 0.5 mg/L (FEU). A D-dimer result <0.5 mg/L (FEU) was considered negative and a D-dimer result ≥0.5 mg/L (FEU) was considered positive.

Patients with a positive D-dimer result and/or a high PTP were evaluated by imaging methods, e.g. spiral CT and/or VQ scan. Patients with a negative D-dimer result and a low or moderate PTP (these patients underwent imaging at the physician's discretion), and patients with negative imaging results, were followed for three months to evaluate potential development of PE.

The overall prevalence of PE in those patients available for final analysis was 13.8% (89/647). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95% confidence limits (CL) were obtained with the INNOVANCE® D-Dimer clinical cutoff of 0.5 mg/L (FEU).

All Patients

Instrument	PE Patients (n)	Cutoff mg/L FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
BCS [®] /BCS [®] XP System	647	0.5	98.9 (93.9 – 100.0)	39.6 (35.5 – 43.8)	99.6 (97.5 – 100.0)

Patients with low and moderate pre-test probability

Instrument	PE Patients (n)	Cutoff mg/L FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
BCS [®] /BCS [®] XP System	616	0.5	98.6 (92.5 – 100.0)	40.4 (36.3 – 44.7)	99.6 (97.5 – 100.0)

CL = lower and upper 95 % confidence limits



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics
c/o Ms Kathleen Dray-Lyons
Manager, Regulatory Affairs
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714

OCT 29 2009

Re: k091916

Trade/Device Name: INNOVANCE® D-Dimer
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation product assays
Regulatory Class: Class II
Product Code: DAP
Dated: October 28, 2009
Received: October 29, 2009

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

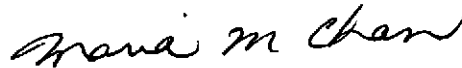
Page 2 – Ms. Kathleen Dray-Lyons

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Maria M. Chan".

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091916

Device Name: **INNOVANCE® D-Dimer**

Indications For Use:

INNOVANCE® D-Dimer:

For the quantitative determination of cross-linked fibrin degradation products (D-dimers) in human plasma on Siemens Healthcare Diagnostics and Sysmex® Coagulation Systems. The INNOVANCE® D-Dimer assay is intended for use in conjunction with a non-high clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease and as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)].

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

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Maria McChen
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K091916